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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,125	12/22/2003	Peter M. Bonutti	2500DV2CN2DV3CN6	7494

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Kimberly V. Perry, Esq.
U.S. Surgical
A Division of Tyco Healthcare Group, LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/743,125

Applicant(s)

BONUTTI, PETER M.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on March 8, 2007, amended claims 11-15 and new claims 20-21 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 of copending Application No. 10/729,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 9 of copending Application No. 10/729,634.

Claims 1 and 11 of copending application No. 10/729,634 recite a retractor comprised of a shaft, inflatable bladder disposed at an end of the shaft where the bladder has an inflatable shape selected from the group consisting of circular, oval, eccentric, oblong, conical, wedge-shaped, V-shaped and multiple lobes, along with other features. Claim 11 of the instant application recites a retractor comprised of a shaft and an inflatable bladder that is eccentric or eccentrically mounted on the shaft. Furthermore, claims 13-15 of the instant invention are identical to claims 4-6 of copending Application No. 10/729,634, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/743,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 7 of copending Application No. 10/743,192. The combination of claims 1 and 7 disclose a similar retractor of the instant invention differing only in the shape of the inflatable bladder. Furthermore, claims 13-15 of the instant invention are identical to claims 2-4 of copending Application No. 10/743,192, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-21 of copending Application No. 10/729,768 (Note: Claims 15-21 refer to the most recent claim amendment on file in Application No. 10/729,768 - filed July 1, 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claim 1 and 21 of copending Application No. 10/729,768. Claim 1 of copending Application No. 10/729,768 recites an apparatus comprised of a shaft and an inflatable bladder wherein the inflatable bladder has a shape selected from the group consisting of: eccentric, conical and wedge-shaped, along with other features. Claims 13-15 are identical to claims 16-18 of copending Application No. 10/729,768, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 20-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 20-21 fail to further limit claim 11, which already has the limitation "wherein the at least one inflatable bladder is configured to cause the region of the shaft to become rigid".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,921,478 to Solano et al. in view of U.S. Patent No. 4,295,464 to Shihata.

In regard to claims 11-15 and 20-21, Solano et al. disclose a retractor comprising: a shaft 14 including at least one flexible portion 36; an a plurality of inflatable bladders 16 disposed on the shaft, at least one of the inflatable bladders being configured to cause a region of the shaft to become more rigid when the at least one inflatable bladder is inflated (see Figs. 2 and 5a-c and Col. 4, Lines 25-67). Solano et al. are silent with respect to a cannula having a passage which receives the shaft to deploy the bladder at a target site in tissue. Shihata teaches of an analogous apparatus having a cannula 102 which has a passage that receives a catheter 101 therethrough. It would have been obvious to one skilled in the art at the time the invention was made to use a cannula with the apparatus of Solano et al. to aid in placing the shaft 14 at a desired site within the body and thus deploy the inflatable bladders 16 at a target site in tissue as taught by Shihata.

Claims 11-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,295,464 to Shihata.

In regards to claims 11-15 and 20-21, Shihata discloses an apparatus comprising: a shaft 101 including at least one flexible portion (see Col. 5, Lines 45-60 and Col. 7, Lines 30-36); an inflatable bladder 107 disposed on the shaft, at least one of the inflatable bladders being configured to cause a region of the shaft to become more rigid when the at least one inflatable bladder is inflated; and a cannula 102 having a passage which receives the shaft to deploy the bladder at a target site in tissue and wherein the inflatable bladder is shaped so that it expands into an eccentric shape when inflated by fluid pressure introduced (see Fig. 2). Shihata discloses the claimed invention except for a plurality of inflatable bladders disposed on the shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to configure more than one inflatable bladder on the shaft, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments filed March 8, 2007 have been fully considered but they are not persuasive.

Applicants states that Shihata fails to disclose or suggest at least one of the inflatable bladders being configured to cause a region of the shaft to become more rigid when the at least one inflatable bladder is inflated. However, the inflatable bladder 107 of Shihata is connected to dislodger catheter 101 and is used to apply a downward force sufficient to dislodge a stone from the inner walls. Thus the inflatable bladder would inherently be made more rigid when inflatable to enable the bladder to perform its

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desired function. Furthermore, Shihata teaches that the bladder and shaft may be made from any material generally known in the arts (see Col.6, Lines 1-13 and Col.7, Lines 30-40). Thus, as broadly as claimed, Shihata meets the limitation of the recited claims.

Furthermore, applicant's arguments with respect to claims 11-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK *ml*

5/17/07



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700